

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-46. (Cancelled)

47. (Previously Presented) A process for making a pharmaceutical dosage form comprising the steps of:

a) introducing a composition comprising

(i) copolymer of Ammonio methacrylate Copolymer Type A (Eudragit RL) or Ammonio methacrylate Copolymer Type B (Eudragit RS) present in an amount of about 10 to about 80% w/w;

(ii) at least one dissolution modifying excipient selected from a swellable solid, present in a total amount of about 20% to about 65% w/w optionally in combination with a second dissolution modifying excipient selected from the group consisting of a disintegrant, a water soluble filler, a low molecular weight solute, or a non-reducing sugar;

(iii) a lubricant present in an amount of about 5% to about 25% w/w; and optionally a surfactant present in an amount of 0 to about 10%, a plasticizer present in an amount of 0 to about 10% w/w and/or a processing agent present in an amount of 0 to about 10% w/w; simultaneously, and at substantially the same location, into an elongated hot melt extruder;

b) mixing said copolymer and said excipient composition in the hot melt extruder to form a homogeneous composition therein and ejecting the homogeneous composition in the form of a strand from the hot melt extruder though a die at a location remote from said same location at which the copolymer and said excipient composition are introduced;

c) cutting the strand into pellets;

d) introducing said pellets into an injection molder and forming subunits of a thin-walled capsule compartment, a solid matrix subunit or a linker, from said pellets by injection molding.

48. (Previously presented) The process according to Claim 47, in which the hot melt extruder is maintained at a temperature not lower than the copolymer and said excipient composition melting points.

49. (Previously presented) The process according to Claim 49, in which the temperature in the hot melt extruder gradually increases along the length of the hot melt extruder, from said same location at which the copolymer and an excipient composition are introduced, to the die.

50. (Previously presented) The process according to Claim 49, in which the hot melt extruder comprises an elongated barrel having first and second opposite ends, and twin screws within the barrel for propelling copolymer and said excipient composition along the length of the interior of the barrel, said substantially same location at which the copolymer and said excipient composition are introduced is located adjacent the first end of the barrel, and said die is located adjacent the second end of the barrel.

51. (Previously presented) The process according to Claim 47 wherein the pharmaceutical dosage forms are assembled using said capsule compartments as components of said dosage forms.

52. (Previously presented) The process according to Claim 51 wherein the said capsule compartments of the assembled dosage form are connected together by at least one weld where adjacent parts of said components are in contact, or are mechanically joined in an assembled dosage form.

53. (Currently amended) The process according to Claim [[1]] 47 wherein the copolymer is Ammonio methacrylate Copolymer Type A.

54. (Currently amended) The process according to Claim [[1]] 53 wherein the copolymer is present in an amount of about 15 to about 50% w/w.

55. (Previously Presented) The process according to Claim 54 wherein the copolymer is present in an amount of about 20 to about 40% w/w.

56. (Previously presented) The process according to Claim 47 wherein the surfactant is present in an amount of less than 2% w/w.

57. (Previously presented) The process according to Claim 65 wherein the surfactant is sodium dodecyl sulphate or is a block copolymer of ethylene oxide and propylene oxide.

58. (Previously presented) The process according to Claim 47 wherein the lubricant is stearyl alcohol, glycerol monostearate (GMS), talc, magnesium stearate, silicon dioxide, amorphous silicic acid, or fumed silica; and combinations or mixtures thereof.

59. (Previously Presented) The process according to Claim 58 wherein the lubricant is stearyl alcohol.

60. (Previously presented) The process according to Claim 59 wherein the stearyl alcohol is present from about 10 to about 15% w/w.

61. (Previously Presented) The process according to Claim 47 wherein the lubricant is stearyl alcohol present from about 10 to about 15% w/w.

62. (Previously Presented) The process according to Claim 53 wherein the lubricant is stearyl alcohol present from about 10 to about 15% w/w.

63. (Currently amended) The process according to Claim 47 wherein the swellable solid is selected from the group consisting of ethyl cellulose, cellulose acetate phthalate[[;]], hydroxypropyl cellulose, hydroxypropylmethyl cellulose, and hydroxypropylmethyl cellulose phthalate, and combinations or mixtures thereof.

64. (Previously Presented) The process according to Claim 47 wherein the swellable solid is at least one of a hydroxypropyl cellulose, or a hydroxypropylmethyl cellulose, or a combination or mixture thereof.

65. (Currently amended) The process according to Claim 47 wherein the dissolution modifying excipient is a swellable solid composed of a blend of hydroxypropyl cellulose polymers, each having a differing molecular weight, ~~present in a total amount of about 30% to about 80% w/w.~~

66. (Currently amended) The process according to Claim 65 wherein the blend of hydroxypropyl cellulose polymers comprises [[is]] a hydroxypropylcellulose having a molecular weight of about 80,00 mw (Klucel EF) and a hydroxypropylcellulose having a molecular weight of about 140,000 mw (Klucel JF).

67. (Currently amended) The process according to Claim 65 wherein the blend of hydroxypropyl cellulose polymers comprises [[is]] a hydroxypropylcellulose having a molecular weight of about 80,00 mw (Klucel EF) and a hydroxypropylcellulose having a molecular weight of about 370,00 mw (Klucel GF).

68. (Currently amended) The process according to Claim 65 wherein the blend of hydroxypropyl cellulose polymers comprises [[is]] a hydroxypropylcellulose having a molecular weight of about 140,000 mw (Klucel JF) and a hydroxypropylcellulose having a molecular weight of about 370,00 mw (Klucel GF).

69. (Previously Presented) The process according to Claim 47 wherein the second dissolution modifying excipient is a non-reducing sugar, a low molecular weight solute, or a water soluble filler.

70. (Previously Presented) The process according to Claim 69 wherein the second dissolution modifying excipient is selected from the group consisting of xylitol, mannitol, lactose, starch, and sodium chloride, and combinations or mixtures thereof.

71. (Previously Presented) The process according to Claim 47 wherein the second dissolution modifying excipient is a disintegrant.

72. (Previously Presented) The process according to Claim 71 wherein the disintegrant is selected from the group consisting of sodium starch glycollate, croscarmellose sodium, crospovidone (cross-linked polyvinyl pyrrolidone), copovidone, polyvinyl pyrrolidone; and combinations or mixtures thereof.

73. (Previously presented) The process according to Claim 47 wherein the plasticizer is triethyl citrate (TEC), tributyl citrate, acetyl triethyl citrate (ATEC), acetyl tributyl citrate (ATBC), dibutyl phthalate, dibutyl sebacate (DBS), diethyl phthalate, vinyl pyrrolidone glycol triacetate, polyethylene glycol, polyoxyethylene sorbitan monolaurate, propylene glycol, or castor oil; and combinations or mixtures thereof.

74. (Previously presented) The process according to Claim 47 wherein the

processing agent is talc, present in an amount of about 1 to about 5 % w/w.

75. (Previously presented) The process according to Claim 47 which further comprises an absorption enhancer.

76. (Previously presented) The process according to Claim 75 wherein the absorption enhancer is chitosan, lecithin, lectin, a sucrose fatty acid ester, Vitamin E-TPGS; and combinations or mixtures thereof.

77. (Currently amended) The process according to Claim 47 wherein the copolymer is Ammonio methacrylate Copolymer Type A present in an amount of about 15 to 50% w/w, ~~and in the excipient composition~~ the lubricant is stearyl alcohol, and the swellable solid is hydroxypropyl cellulose or a blend of hydroxypropyl cellulose's having a differing molecular weights.

78. (Currently amended) The process according to Claim 77 wherein the ~~swellable solid is dissolution modifying excipient is a swellable solid composed of a be of~~ blend of hydroxypropyl cellulose polymers, each having a differing molecular weight ~~present in a total amount of about 30% to about 80% w/w.~~

79. (Previously presented) The process according to Claim 78 wherein the blend of hydroxypropyl cellulose polymers is a hydroxypropylcellulose having a molecular weight of about 80,00 mw (Klucel EF) and a hydroxypropylcellulose having a molecular weight of about 140,000 mw (Klucel JF).

80. (Previously presented) The process according to Claim 78 wherein the blend of hydroxypropyl cellulose polymers is a hydroxypropylcellulose having a molecular weight of about 80,00 mw (Klucel EF) and a hydroxypropylcellulose having a molecular weight of about 370,00 mw (Klucel GF).

81. (Previously presented) The process according to Claim 78 wherein the blend of hydroxypropyl cellulose polymers is a hydroxypropylcellulose having a molecular weight of about 140,000 mw (Klucel JF) and a hydroxypropylcellulose having a molecular weight of about 370,00 mw (Klucel GF).

82. (Previously presented) The process according to Claim 78 wherein the blend of hydroxypropyl cellulose is of equal % w/w.

83. (Previously presented) The process according to Claim 47 in which the subunits of a thin-walled capsule compartment, has a wall with a thickness in the range of about 0.1-0.8 mm.

84. (Currently amended) The process according to Claim 47 in which the subunits of a thin-walled capsule compartment, a solid matrix subunit or a linker, ~~a shell wall, a linker or a capsule subunit~~ are comprised of a homogenous composition selected from the group consisting of which is:

#	Formulations	% w/w
1.	Ammonio methacrylate Copolymer Type A HPC of 370,000 mw (Klucel GF) Lactose Stearyl alcohol	25.00 50.00 13.00 12.00
2.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol	35.00 40.00 13.00 12.00
3.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol	25.00 63.00 12.00
4.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	25.00 31.50 31.50 12.00
5.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol	25.00 50.00 13.00 12.00
6.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol Titanium dioxide	25.00 61.00 12.00 2.00
7.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Stearyl alcohol	24.00 50.00 12.00

	Succinic acid	13.00
8.	Ammonio methacrylate Copolymer Type A HPC of 80,000 mw (Klucel EF) Lactose Stearyl alcohol SDS	24.00 50.00 13.00 12.00 1.00
9.	Ammonio methacrylate Copolymer Type A Ammonio methacrylate Copolymer Type B HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	21.60 2.40 32.00 32.00 12.00
10.	Ammonio methacrylate Copolymer Type A Ammonio methacrylate Copolymer Type B HPC of 80,000 mw (Klucel EF) HPC of 140,000 mw (Klucel JF) Stearyl alcohol	2.40 21.60 32.00 32.00 12.00

85. (New) The process according to Claim 65 wherein the blend of hydroxypropyl cellulose polymers each having a differing molecular weight is of equal % w/w.